

REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

Claims 1-32 remain pending in the present application.

Applicant notes with appreciation the Examiner's indication that claim 6 would be allowable if rewritten in independent form. At this time, the Examiner's suggestion has not been adopted, because the base claim from which claim 6 depends is believed to be patentable over the cited references for the reasons presented below.

I. Request for Acknowledgement of Priority Claim

The present application claims priority under 35 U.S.C. § 119(e) from U.S. provisional patent application no. 60/139,424 filed June 15, 1999. The Examiner's attention is directed to the Inventors' Declaration submitted with the original filing papers in which this priority claim is made. The specification, as amended on August 8, 2002, makes specific reference to the priority document. Accordingly, Applicant again respectfully requests acknowledgment of the priority claim.

II. Change of Correspondence Address

The Examiner's attention is directed to the Change of Address Notice filed on May 6, 2002. It appears, however, that this Change of Correspondence Address was not entered into the Patent Office records, because the April 9, 2003 Amendment was mailed to the incorrect, old address. To correct this problem, a new Change of Correspondence Address is submitted with this Response. This new Change of Correspondence Address form executed by the undersigned attorney of record indicates the present application should be assigned to the address associated with Customer No. 30031. The Examiner's assistance in ensuring that the correspondence address and patent office PAIR system are updated to reflect this new address is greatly appreciated.

III. Rejection of the Claims Under 35 U.S.C. § 112, Second Paragraph

Claims 1-32 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The independent claims in the present application state that “the average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur.” The Examiner is of the opinion that this language is vague because it is not understood how it is possible to determine an “average tidal volume” irrespective of a period of time. Applicant respectfully traverses this rejection for the reasons presented below.

To understand what is mean by “average tidal volume,” one must first understand the term “tidal volume”. *Tidal volume* is the volume of gas inspired or expired during a respiratory cycle. It is represented by the gray areas in FIG. A shown below. More specifically, FIG. A shows two respiratory cycles, and, thus, two separate tidal volumes, one for each respiratory cycle.

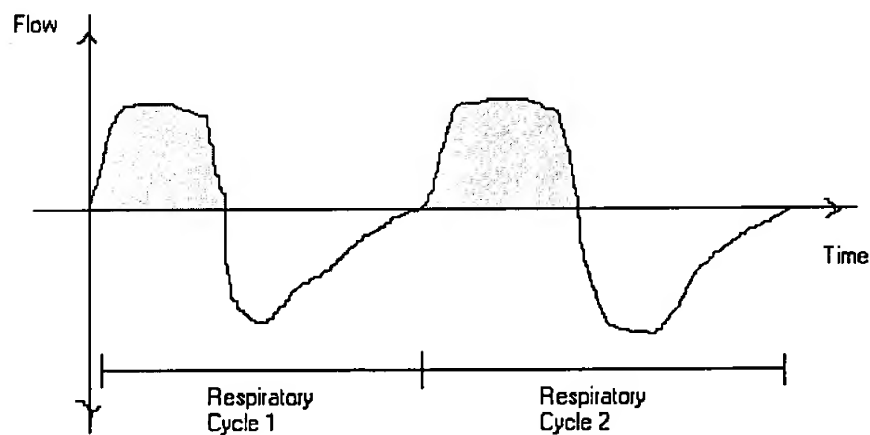


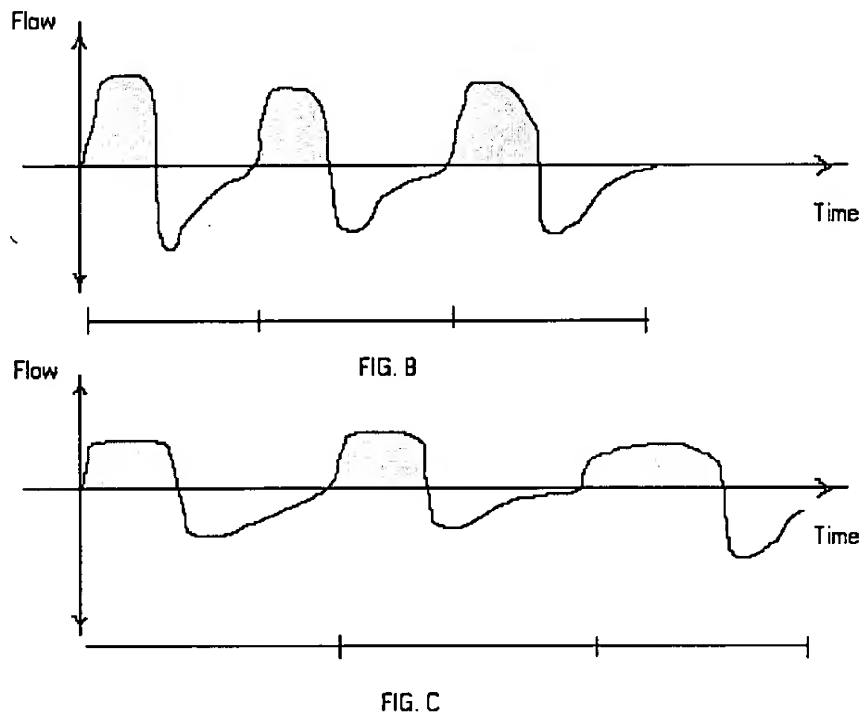
FIG. A

It can be readily appreciated that during any two respiratory cycles, the tidal volume of the patient is often different, because it is difficult, if not impossible, for a person to breathe the same volume repeatedly. It can also be appreciated that the duration of each respiratory cycle is often different for the same reason.

As recited in the independent claims, the present invention determines an average of the tidal volumes over a plurality of inspiratory phases of the respiratory cycles. To determine this average, two variables must be known: (1) the tidal volume during each inspiratory phase,

i.e., the gray areas in each respiratory cycle in FIG. A, and (2) the number of respiratory cycles that are included in the plurality of cycles. For example, if a person has a tidal volume of 485 cubic centimeters (cc) in a first respiratory cycle, 510 cc in the next cycle, and 505 cc in the third cycle, the average tidal volume for that person is 500 cc. $((485 \text{ cc} + 510 \text{ cc} + 505 \text{ cc})/3 = 500 \text{ cc})$. In determining the average tidal volume, it does not matter how long it takes the person to take the three breaths.

Applicant submits that the Examiner appears to be misinterpreting the term “average” in the phrase “average tidal volume” to require a time component, i.e., that the tidal volumes be compared against some period of time. This is simply not the case. For example, FIGS. B and C below illustrate three respiratory cycles. It can be appreciated that the duration of the respiratory cycles in FIG. B is much less than of FIG. C. However, the average tidal volume for the respiratory cycles in FIGS. B and C are nearly the same, i.e., the average size of the gray areas in FIG. B is approximately the same as the average size of the gray areas in FIG. C.



Because the “average tidal volume” is measured over the number of inspiratory phases, and not some period of time, it is possible for two sets of respiratory cycles to have vastly different duration yet have the same average tidal volume. Moreover, because the “average tidal volume” is determined based on the number of inspiratory cycles and not time, it is logical and consistent to define this phrase in the claims as being determined “irrespective of a period of time during which the plurality of inspiratory phases occur.”

For the reasons presented above, applicant submits that the claims are not indefinite. Accordingly, applicant respectfully requests that the above rejection of claims 1-32 be withdrawn.

II. Rejection of the Claims based on the Cited References

Claims 1-4, 13, 14, 16-25, 27 and 30-32 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,041,780 to Richard et al. (“the ‘780 patent”). In addition, claims 5, 7-12, 15, 26, 28, and 29 stand rejected under 35 U.S.C. § 103 as being unpatentable over the ‘780 patent. Applicant respectfully traverses these rejections for the reasons presented below.

A claim is anticipated only if each and every element set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

According to M.P.E.P § 706.02(j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and

not based on the applicant's disclosure. *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). See also M.P.E.P. § 2143.03.

According to the Examiner as set forth on page 4 of the April 9, 2003 Official Action, the '780 patent teaches at column 4, line 65, through column 5, line 5, determining an average tidal volume and teaches at column 4, line 28, through column 5, line 5, comparing the average tidal volume to a predetermined target volume and adjusting the pressure based on this comparison. Applicant respectfully disagrees.

The '780 patent does not teach comparing an *average tidal* volume to a predetermined target volume. Instead, it teaches comparing a *minute* volume to a target minute volume. For example, column 5, lines 1-17, of the '780 patent explicitly states that the actual *minute* volume is compared to the adjusted *minute* volume. The IPAP pressure is then adjusted based on this comparison.

Because of the misunderstanding of the phrase "average tidal volume", as evidenced by the rejection of the claims under 35 U.S.C. § 112, second paragraph, discussed above, the Examiner appears to be improperly equating the claimed "average tidal volume" with the "*minute* volume" taught by the '780 patent. Applicant submits that there are significant differences between "average tidal volume" and "minute volume".

Minute volume is a parameter well known in the respiratory field as the amount of gas inspired by the patient over the course of one minute. It is often also referred to as "minute ventilation." Mathematically, the minute volume is calculated by multiplying the patient's tidal volume (or average tidal volume) by the breath rate, which is also referred to as the breathing frequency. See, e.g., column 3, lines 3-7, column 4, lines 17-21, and column 4, lines 65, through column 5, line 1, of the '780 patent. Thus, determining the "minute volume" requires additional steps not necessary in calculating "average tidal volume".

On a fundamental level, "average tidal volume" represents a better indication of the amount of treatment being provided to the patient's lungs than "minute volume." This is so because the "average tidal volume" is a measure of the actual volume of fluid that enters the patient. "Minute volume," by definition, is determined based, in part, on the patient's own

respiratory rate. This rate is determined by the patient's respiratory drive, which is naturally variable. As a result, "minute volume" does not give an accurate representation of what amount of gas is filling the lungs to treat the patient.

An example may further serve to explain the differences between controlling IPAP based on "average tidal volume" as opposed to "minute volume." Suppose that a patient is breathing at a first respiratory rate. Next, suppose that the patient attempts to slow down their respiratory rate. This can occur, for example, when the patient relaxes his or her breathing. It also typically occurs when a patient falls asleep, because their metabolic rate is reduced during sleep.

In a "minute volume" controlled device, the reduction in respiratory rate will be seen as a decrease in the minute volume. As a result, the "minute volume" based ventilator will increase the IPAP to push the patient's minute volume back up to the target level. This is a very undesirable situation, because an increase in IPAP is exactly the opposite of what someone who is relaxing their breathing or trying to fall asleep would want. In fact, the '780 patent attempts to address this problem by including a special step, i.e., step 52, in FIG. 2B, that adjusts the target minute ventilation level down when it appears that the patient is attempting to reduce their respiratory rate.

In an "average tidal volume" controlled device, such as the present invention, the same reduction in respiratory rate has no impact on the IPAP control, because the patient's respiratory rate is not taken into consideration. Thus, there is no need for any special control of the target tidal volume.

Because the basic mathematical differences between "average tidal volume" and "minute volume" as well as the fundamental differences noted above, applicant submit that the use of minute ventilation in the '780 patent does not anticipate the use of "average tidal volume" in the present invention. Furthermore, these mathematical and fundamental differences are sufficient that one of ordinary skill in the art would not consider it obvious to modify a system that controls IPAP based on "minute volume" so that it controls IPAP based on "average tidal volume." There is simply no teaching or suggestion of such modification in the cited references.

HILL et al. -- Appln. No.: 09/586,054

For the reasons presented above, applicant respectfully submit that independent claims 1, 7, 13, 19, 23, and 27 are not anticipated or rendered obvious by the cited references. In addition, claims 2-5, 8-12, 14-18, 20-22, 24-26 and 28-32 are also not anticipated or rendered obvious due to their dependency from one of the above-noted independent claims. Accordingly, applicant respectfully requests that the above rejection of these claims be withdrawn.

All objections and rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and a Notice to the effect is earnestly solicited.

Respectfully submitted,

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Attached: Change of Correspondence Address Form.